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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,971	09/24/2003	Nathan A. Winslow	5490-000337	4885

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EXAMINER

BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/669,971	Applicant(s) WINSLOW, NATHAN A.	
	Examiner Javier G. Blanco	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/2003; 10/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims.
 - a. Therefore, the “blasted finish” (see claim 7) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.
 - b. Therefore, the “jig to resect the portion of the humeral head” (see claim 23) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.
 - c. Therefore, the “trial implant” (see claim 25) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

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be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claims 16 and 19 are objected to because of the following informalities:
 - a. Regarding claim 16, please delete “articulating” (see line 1). Appropriate correction is required.
 - b. Regarding claim 19, please substitute “in a lateral region so as to” (see line 7) with --in a lateral region of the humeral head so as to--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - a. Regarding each of claims 23-25, “said preparing step” (see line 1) or “said implanting step” (see line 1) lacks antecedent basis.
 - b. Regarding claim 25, the limitation “implanting a trial implant, similar to the implant, before the implant is implanted to reduce a joint at the implant site” (see lines 2-3) is vague, rendering claim 25 indefinite. How does “implanting a trial implant” achieve “to reduce a joint at the implant site”?

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 6, 8-10, 12, 13, 15, 17-21, and 23-25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Maroney et al. (US 2002/0099445 A1; cited in Applicant's IDS).

Caveat: It seems, from the disclosure, that Applicant have been using the terms “resurfacing” and “resection” interchangeably (for example, see paragraph 0027). Figure 4 shows humeral head 40 completely removed, and the area of the greater tubercle partially to completely removed. The Examiner will broadly interpret “resurfacing” and “resecting” as having the same (or similar) meaning or connotation.

Referring to Figures 1-3 and 6-15, Maroney et al. disclose a method for resurfacing a humeral head of an implant site, the method comprising:

- (i) Resurfacing the humeral head (see Figures 7 and 8, and optionally Figures 13 and 14; see entire document, particularly paragraphs 0028-0031);
- (ii) Positioning a resurfacing humeral head implant (head component 14 comprising tapered post 24, glenoid-bearing portion 30, and acromion-bearing portion 32 having an inner concave surface) on the resurfaced surface of the humeral head (see Figures 2, 3, and 15; see entire document, particularly paragraphs 0025-0030); and
- (iii) Positioning an extended articulating surface (i.e., acromion-bearing portion 32) of the resurfacing humeral head implant in a lateral region (i.e., greater tubercle region/area) so as to

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articulate with at least one of a bone (i.e., acromion 36) and a ligament (see Figures 2, 3, and 15; see entire document, particularly paragraphs 0025-0031).

Regarding claims 23-25, Maroney et al. disclose (see Figures 6, 7, and 11-14; see entire document, particularly paragraphs 0032, 0037-0039, and 0049) using a jig (i.e., a guide) and a trial implant. It should be noted that, according to the instant application, the use of a jig is disclosed as an option (see 10/669,971 at paragraph 0027).

7. Claims 1-8, 10, 12, 13-15, 17-20, and 23-25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the disclosure of Copeland™ Humeral Resurfacing Head (Biomet Orthopedics, Inc.: 2000 brochure).

Caveat: It seems, from the disclosure, that Applicant have been using the terms “resurfacing” and “resection” interchangeably (for example, see paragraph 0027). Figure 4 shows humeral head 40 completely removed, and the area of the greater tubercle partially to completely removed. The Examiner will broadly interpret “resurfacing” and “resecting” as having the same (or similar) meaning or connotation.

Referring to Figures 1-18, and the pictures on page 1, the brochure discloses a method for resurfacing a humeral head of an implant site, the method comprising:

- (i) Resurfacing the humeral head (see Figures 1-15; see entire document, particularly pages 3-7);
- (ii) Positioning a resurfacing humeral head implant (Copeland™ Humeral Resurfacing Head comprising a dome-shaped outer surface, a concave inner surface, and a tapered post having flutes and a blasted finish) on the resurfaced surface of the humeral head (see Figures 1-17; see entire document, particularly pages 3-8); and

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(iii) Positioning an extended articulating surface (i.e., the circumferential edge) of the resurfacing humeral head implant in a lateral region (a “lateral region” is broadly interpreted) so as to articulate with at least one of a bone and a ligament (see Figures 16 and 17; see entire document).

It should be noted that, from the claim language, an arbitrary line or boundary distinguishes/defines the “extended articulating surface”. It should also be noted that the circumferential edge of the implant “articulates with least one element of an coracoacromial arch” (see Figure 16). Regarding claims 23-25, the brochure shows (see Figures 11-15) using a jig (i.e., a guide) and a trial implant. It should be noted that, according to the instant application, the use of a jig is disclosed as an option (see 10/669,971 at paragraph 0027).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 11, 16, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maroney et al. (US 2002/0099445 A1; cited in Applicant’s IDS) in view of Pappas et al. (US 4,470,158).

Maroney et al. disclose the invention as claimed in claims 1-4, 6, 8-10, 12, 13, 15, 17-21, and 23-25 (see 102(b) rejection above). Maroney et al. did not particularly disclose said extended articulating surface as having “a planar “V” shaped inner surface”. However, this is well known

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in the art. For example, Pappas et al. disclose joint prostheses comprising articulating surfaces having planar “V” shaped inner surfaces (**Figure 2**: inner surface of component 11; **Figures 37-41 and 63**: component/flange 100 comprises an extended articulating surface 106 having a planar “V” shaped inner surface; and **Figure 50**: inner surface of plate section 152) in order to maximize the prosthesis-to-bone contact area, minimize tipping effects resulting from eccentric loads, and minimize compressive stress on the bone (see column 6, lines 39-50 and lines 55-58; column 21, lines 8-15; and column 23, line 54 to column 24, line 9). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of joint prostheses comprising articulating surfaces having planar “V” shaped inner surfaces, as taught by Pappas et al., with the joint prosthesis of Maroney et al., in order to maximize the prosthesis-to-bone contact area, minimize tipping effects resulting from eccentric loads, and minimize compressive stress on the bone.

NOTE: Looking to Applicants’ specification (see paragraphs 0022 and 0027), there is no criticality in the use of a “planar “V” shaped inner surface”. Furthermore, the Applicant admits in the present application that “the resection 52 may be of various other shapes or configurations” (see paragraph 0027).

Conclusion

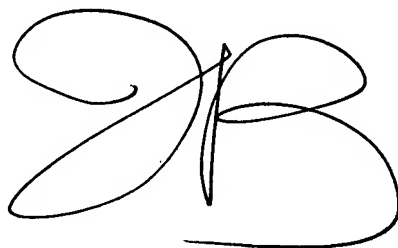
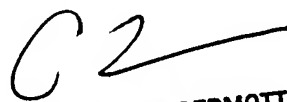
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

November 7, 2005

A large, stylized handwritten signature in black ink, consisting of a large loop followed by a vertical stroke and another large loop.A handwritten signature in black ink, appearing to be 'C2' followed by a horizontal line.

CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700